UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/679,642 | 10/06/2003 | Henrik Bengtsson | 6517.200-US | 3938 |

7590 01/08/2007

Reza Green, Esq.
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540

| EXAMINER | |
|---|---|
| MACNEILL, ELIZABETH | |
| **ART UNIT** | **PAPER NUMBER** |
| 3767 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 01/08/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/679,642 | BENGTSSON, HENRIK | |
| | Examiner | Art Unit | |
| | Elizabeth R. MacNeill | 3767 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *9-11,18-20,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 12-17, 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/10/04; 2/25/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 22-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 November 2006.

2. Claims 9-11 and 18-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 November 2006. In the response, the applicant did not indicate which claims were readable on the elected Species A (Figures 1-5). Claims 9 and 10 are drawn to the embodiment of Figure 7. Claims 11 and 18-20 are drawn to the embodiment of Figures 9A-10B.

### *Drawings*

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the adhesive means (115,215) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-7, 12-17, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Aceti et al (US 7,004,928).

Regarding claim 1, Aceti teaches a needle device (10) comprising: a mounting surface adapted for application to the skin of a subject, adhesive means (Fig 29b) arranged on the mounting surface for adhering the needle device to the skin of the subject, a plurality of needles (46), each needle comprising a distal pointed end adapted to penetrate the skin of the subject, wherein each needle has a first position in which the distal end is retracted relative to the mounting surface, and a second position in which the distal end projects from the mounting surface, the needles being arranged such that at least one needle can be moved from its first to its second position or from its second to its first position with at least one other needle not performing the same movement. Figs 1-4.

Regarding claim 2, needle actuating means (22) are associated with a plurality of needles, the needle actuating means being operatable between a first actuating position and a second actuating position, whereby a first associated needle is moved from its first to its second position and a second associated needle is moved from its second to its first position.

Regarding claim 3, the needle actuating means are operatable between a plurality of actuating positions, each operation between actuating positions being associated with operation of a corresponding pair of needles between their first and second respectively second and first positions.

Regarding claim 4, the needle actuating means is operatable between an initial position, in which all associated needles are in their first position, and an actuating position, whereby a needle is moved from its first to its second position.

Regarding claim 5, the needle actuating means is operatable between an actuating position, in which an associated needle is in its second position, and an end position in which all associated needles are in their first position.

Regarding claim 6, each of the associated needles are connected to a needle carrier (266), the actuation means comprising moveable control means (268) in engagement with or operatable to come into engagement with the needle carriers, the position of the control means controlling operation of the needles between their respective first and/or second positions.

Regarding claim 7, the needle carriers are associated with biasing means (176) for moving the respective needle from its first to its second position by a force generated by the biasing means, release of the biasing means being controlled by movement of the control means.

Regarding claim 12, the device comprises means (teeth on 282) preventing a needle from being moved from its first to its second position more than once.

Regarding claim 13, the device comprises a common fluid conduit means (234), wherein a plurality of the needles are hollow having a distal and a proximal opening (44), the proximal opening being in fluid communication with the common fluid conduit means when the needle is in its second position.

Regarding claim 14, the proximal opening of a hollow needle is not in fluid communication with the common fluid conduit means when the needle is in its first position.

Regarding claim 15, the device contains a reservoir ("pharmaceutical agent delivery microchannel") adapted to contain a liquid drug and comprising an outlet in fluid communication with the common fluid conduit means.

Regarding claim 16, the device contains expelling means (needle outlet and controller) for expelling a drug out of the reservoir and through the skin of the subject via the common fluid conduit means and a hollow needle.

Regarding claim 17, the common fluid conduit means comprises a fluid inlet means (44).

Regarding claim 21, the plurality of needles comprises at least two hollow infusion needles, the hollow infusion needles being arranged such that only one infusion needle can be positioned in the second position at a given time.

### *Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-8, 12 ,and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groth (WO 01/93927, cited by applicant) in view of Aceti et al. Regarding claim 1, Groth teaches a needle device (1) comprising: a mounting surface adapted for application to the skin of a subject, a plurality of needles (2), each needle comprising a distal pointed end adapted to penetrate the skin of the subject, wherein each needle has a first position in which the distal end is retracted relative to the mounting surface, and a second position in which the distal end projects from the mounting surface, the needles being arranged such that at least one needle can be moved from its first to its second position or from its second to its first position with at least one other needle not performing the same movement. Figs 1-4.

Groth fails to teach adhesive means arranged on the mounting surface for adhering the needle device to the skin of the subject. Aceti teaches adhesive means (Fig 29b) used to secure the infusion/sampling device onto the skin of a patient in order to stabilize the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use adhesive means to stabilize the device of Groth onto the patient's skin.

Regarding claim 2, needle actuating means (3) are associated with a plurality of needles, the needle actuating means being operatable between a first actuating position and a second actuating position, whereby a first associated needle is moved from its first to its second position and a second associated needle is moved from its second to its first position.

Regarding claim 3, the needle actuating means are operatable between a plurality of actuating positions, each operation between actuating positions being associated with operation of a corresponding pair of needles between their first and second respectively second and first positions.

Regarding claim 4, the needle actuating means is operatable between an initial position, in which all associated needles are in their first position, and an actuating position, whereby a needle is moved from its first to its second position.

Regarding claim 5, the needle actuating means is operatable between an actuating position, in which an associated needle is in its second position, and an end position in which all associated needles are in their first position.

Regarding claim 6, each of the associated needles are connected to a needle carrier (3), the actuation means comprising moveable control means (6) in engagement with or operatable to come into engagement with the needle carriers, the position of the control means controlling operation of the needles between their respective first and/or second positions.

Regarding claim 7, the needle carriers are associated with biasing means (11, 7) for moving the respective needle from its first to its second position by a force generated by the biasing means, release of the biasing means being controlled by movement of the control means.

Regarding claim 8, the control means comprises a cam surface (6) with a sloped portion, whereby movement of the sloped portion causes a needle to be moved from its second to its first position against the force of the biasing means.

Regarding claim 12, the device comprises means (pawls on the pawls wheel, see Claim 11) preventing a needle from being moved from its first to its second position more than once.

Regarding claim 21, the plurality of needles comprises at least two hollow infusion needles, the hollow infusion needles being arranged such that only one infusion needle can be positioned in the second position at a given time.

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Aceti et al (US 6,540,675) and Hershberg (US 3,572,336).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

1/4/07

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER